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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,800	09/25/2001	Kenneth Franco	2500-2518	3097

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EXAMINER	
BAXTER, JESSICA R	

ART UNIT	PAPER NUMBER
3731	11

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/966,800	FRANCO ET AL.
	Examiner	Art Unit
	Jessica R Baxter	3731

-- The MAILING DATE of this communication app ars on the cover she t with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/15/2002, 2/12/2002, 11/8/2002, 6/1* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25,28-36,38-68,71-79 and 81-96* is/are pending in the application.

4a) Of the above claim(s) *54-68,71-79,81-93 and 95* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25,28-36,38-53,94 and 96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5,6,8,9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-25, 28-36, 38-53, 94 and 96 are drawn to an anastomosis stent, classified in class 623, subclass 1.1.

   II. Claims 54-68, 71-79, 81-93 and 95, drawn to a tissue plug, classified in class 606, subclass 213.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different functions. The anastomosis stent connects vessels together and the tissue plug seals openings in tissue.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Louis Wu on March 13, 2003 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-25, 28-36, 38-53, 94 and 96. Affirmation of this election must be made by applicant in replying to this Office action. Claims 54-68, 71-79, 81-93 and 95 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or

more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

6. The information disclosure statement filed June 11, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Copies of the references were received, but they were irradiated in the mail and therefore, not considered.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 42-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 42 recites the limitation "the aperture" in line 4. There is insufficient antecedent basis for this limitation in the claim.

10. Claim 47 recites the terms CIS and CSF. It is unclear from the abbreviations what is meant by these terms. Please change "CIS" to --colony stimulating factor--. Please change "CSF" to --collagen in solution--.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1, 2, 6, 7, 12-16, 28-32, 36, 38 and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,001,123 to Lau.

Regarding claims 1, 28-32, 36, 38 and 39, Lau discloses a stent comprising first and second termini, a primary lumen, wherein at least one of the first and second termini is sized to be inserted into an opening in a vessel of a patient, and the stent is comprised of a polyethylene glycol of a molecular weight of about 100 to 20,000 daltons (Column 15 lines 33-36) chemically conjugated to a collagenic material (Column 15 lines 23-31).

Regarding claims 6, 7 and 12-16, Lau discloses that the diameter is about 1- 8 mm (Column 10 lines 17-23) depending on where the stent is placed.

Regarding the limitation "a material that is resorbable by the patient in about a few minutes up to about 90 days", Lau does not specifically disclose the stated time limit, however, the material is the same as claimed and inherently it will function in the same fashion.

13. Claims 1, 12, 28-33, 35, 38 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,874,500 to Rhee et al.

Rhee discloses a stent comprising a material (Column 1 lines 12-20) comprising polyethylene glycol (Column 6 lines 33-45 and Column 11 lines 3-19) chemically conjugated to a collagenic material (Column 11 lines 66-67) of gelatin (Column 12 lines 20-27) or a

glycosaminoglycan polysaccharide (Column 13 lines 18-29) or hyaluronic acid (Column 11 lines 20-34).

Regarding the limitation "a material that is resorbable by the patient in about a few minutes up to about 90 days", Rhee does not specifically disclose the stated time limit, however, the material is the same as claimed and inherently it will function in the same fashion.

14. Claims 1, 2, 12, 21 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,690,684 to McGreevy et al.

McGreevy discloses a stent comprising a material of frozen physiologic saline (Column 3 lines37-50) that absorbs within 10 days (Column 2 line 66-Column 3 line 11).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 1-5, 8, 17, 18, 20, 41, 42, 43 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,056,762 to Nash et al in view of U.S. Patent No. 5,180,392 to Skeie et al.

Nash discloses the claimed invention except for the specific resorbable material. Skeie discloses a resorbable material (polyethylene glycol conjugated with a naturally occurring compound) that is used for an anastomosis stent (Column 3 line 18-Column 4 line 23). It would have been obvious to one having ordinary skill in the art at the time the

invention was made to provide the stent of Nash with the material, as taught by Skeie, as an alternative resorbable material suitable for anastomosis devices.

Regarding claim 43, Nash discloses that sutures are not needed in the method (Column 2 lines 49-51).

17. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhee '500. Rhee discloses the claimed invention except for the specific length of the anastomosis stent. It would have been an obvious matter of design choice to adjust the length of the stent for different sizes of vessels to be anastomosed, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

18. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. '762 in view of Skeie et al '392, as applied to claims 1-5, 8, 17, 18, 20, 41, 42, 43 and 53 above, further in view of U.S. Patent No. 5,944,019 to Knudson et al.

Nash, as modified, discloses the claimed invention except for the stent lumens intersecting perpendicularly to each other. Knudson teaches that the stent lumens may intersect at a perpendicular angle (FIGS. 1A, 1B, 2A, 20). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the lumens of Nash's stent intersect at a perpendicular angle, as taught by Knudson, since the perpendicular angle is an alternative embodiment of the angled anastomosis stent.

19. Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhee '500 in view of U.S. Patent No. 5,527,324 to Krantz et al.

Rhee discloses the claimed invention except for the amount of time it takes for the stent to resorb. Krantz teaches that the composition of an anastomosis stent can be adjusted to dissolve when it is no longer needed. It would have been obvious to one having

ordinary skill in the art at the time the invention was made to adjust the composition of Rhee so that it can be absorbed in the needed amount of time.

20. Claim 40 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. '762 in view of Skeie et al '392 as applied to claims 1-5, 8, 17, 18, 20, 41, 42, 43 and 53 above, and further in view of U.S. Patent No. 5,141,516 to Detweiler.

Nash, as modified, discloses the claimed invention except for the use of a tissue sealant. Detweiler teaches that a tissue sealant is applied to maintain adhesion at an engagement region (Column 6 line 66- Column 7 line 62). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Nash with a sealant in order to maintain engagement between the anastomosed vessels.

21. Claims 44-50, 94 and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. '762 in view of Skeie et al '392 as applied to claims 1-5, 8, 17, 18, 20, 41, 42, 43 and 53 above, and further in view of Detweiler '516 and further in view of U.S. Patent No. 6,495,127 to Wallace et al.

Nash, as modified, discloses the claimed invention except for the specific features of the tissue sealant. Wallace teaches a tissue adhesive with improved strength that includes collagenic material, polyethylene glycol (Column 11 lines 56), and cross-linking (Column 2 lines 15-26). It would have been obvious to one having ordinary skill in the art to replace the adhesive of Nash, as modified, with the adhesive as taught by Wallace in order to improve the strength of the bond between the anastomosed tissues.

22. Claims 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. '762 in view of Skeie et al '392 as applied to claims 1-5, 8, 17, 18, 20, 41, 42, 43 and 53 above, and further in view of Detweiler '516 and further in view of U.S. Patent No. 4,740,534 to Matsuda et al.

Nash, as modified discloses the claimed invention except for specific method of applying the tissue sealant. Matsuda teaches that a tissue adhesive may be applied by spray or by injecting around the tissue to be sealed (Column 5 lines 6-28). It would have been obvious to one having ordinary skill in the art to apply the adhesive, as taught by Matsuda, by spray or injection in order to seal a tissue to another tissue or to seal the device to the surrounding tissue.

Conclusion

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following references are cited to further show the state of the art with respect to similar anastomosis stents and materials:

U.S. Patent No. 5,085,629 to Goldberg et al.
U.S. Patent No. 5,139,505 to Palmieri
U.S. Patent No. 5,306,286 to Stack et al.
U.S. Patent no. 5,464,450 to Buscemi et al.
U.S. Patent No. 5,614,587 to Rhee et al.
U.S. Patent No. 5,643,340 to Nunokawa
U.S. Patent No. 6,334,872 to Termin et al.
U.S. Patent No. 6,468,297 to Williams et al.
PGPUB 2002/0022055 to Signore

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter
Examiner
Art Unit 3731

jrb
April 3, 2003

MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
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